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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,246	LUI, GE MING	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 9/24/08 is acknowledged. Claims 11 and 13-15 are amended. Claims 1-25 are pending in this application. Claims 1-10 and 18-25 are withdrawn with traverse (filed on 12/18/07) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Claims 11-17 are under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 9/24/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The objection of claims 1-10 and 18-25 is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections/Objections Maintained

In view of the amendment filed on 9/24/08, the following rejections are maintained.

Claim Objections

4. Claims 13 and 15 stand objected to because of the abbreviation of HCEC.

On p. 14 of the response, Applicant argues that the abbreviation of HCEC stands for "human corneal endothelial cell" and is defined in the specification. Applicant's arguments have been fully considered but they are not persuasive.

Although the abbreviation of HCEC stands for "human corneal endothelial cell", HCEC could also stand for "Health Careers Evaluation Committee" based on a Google search on "HCEC". Applicants are required to spell out HCEC at the first usage in the claims. Appropriate correction is required.

Claim 7 is objected as depending from a nonelected claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is maintained for the reasons made of record.

On p. 15 of the response, Applicant argues that "RGDS" are the single-letter amino acid code representing arginine, glycine, aspartic acid and serine and submits a page of the Sigma-Aldrich product catalog (attachment A) to support of the argument.

Applicant also argues that although an amino acid sequence of four amino acids would require a SEQ ID NO: and a sequence listing, the peptide of "RGDS" is a recognized cellular reagent and cites US patent Nos. 5853713, 7052711 and 7090496 in support of the argument. Applicant further argues that Applicant has amended "RGDS" at [0013] to identify these four amino acids. Applicant's arguments have been fully considered but they are not persuasive.

In response, although the claims are examined in light of the specification, the recitation of "RGDS" does not reflect a peptide consisting of "arginine, glycine, aspartic acid and serine". A Google search on "RGDS" could result in that "RGDS" stands for a meaning "regards". In addition, each application is judged by its own merit. As previously made of record, the rejection can be obviated by amending the claims to specifically and uniquely identify RGDS, for example, by SEQ ID NO. and function of RGDS. Furthermore, the Examiner is not permitted to waive requirements of the MPEP, therefore, RGDS is required to be represented in the Sequence Listing (see 37 CFR 1.821 (a)-(d)). The fact that there are patents with "RGDS" in them without representing "RGDS" in a Sequence Listing is irrelevant and does not set for a per se exclusion from the Sequence Rules.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-12 and 17 stand rejected under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 5827641 (Parenteau et al. issued on Oct 27, 1998). The rejection is maintained for the reasons made of record.

Claims 11-12 and 17 as amended are drawn to an artificial full thickness cornea transplant support and an artificial cornea transplant comprising a base biopolymer incorporating an attachment reagent comprising one or more the following: laminin, fibronectin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil or heparin sulfate, wherein the biopolymer is molded into the shape of a cornea and seeding or not seeding human corneal endothelial cells onto the biopolymer.

On p. 18 of the response, Applicant argues that Parenteau (the '641 patent) does not teach human corneal endothelial cells used in a complete artificial corneal construct. Applicant argues that Parenteau does not teach incorporation of any attachment reagents to the biopolymer support and does not teach the support is in the shape of a cornea. Applicant further cites *Verdegaal Bros. v. Union Oil Co. of California* in support of the arguments. Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., human corneal endothelial cells) are not recited in the rejected claim(s). Although

the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In contrast, the examiner asserts that Parenteau teaches the claimed invention recited in instant claims 11-12 and 17 because claims 11-12 and 17 do not recite human corneal endothelial cells. In addition, Parenteau does teach incorporation of any attachment reagents to the biopolymer support wherein the support is in the shape of a cornea because Parenteau teaches an cornea equivalent for cornea transplantation comprising endothelial cells seeded on membranes made of biopolymer including collagen IV and coated with heparin (i.e.heparin sulfate) and heparin-binding growth factor (i.e.bFGF or EGF-conjugated with polycarbophil) (see col.5-7;col. 5, lines 21-60; col. 6, lines 50-65 in particular). As previously made of record, the cornea equivalent or transplant of Parenteau encompasses the structures and cell layers of the real cornea (an inner endothelial cell layer, a middle stromal cell-collagen mixture layer and an external epithelial cell layer) and is used for transplantation, so the thickness of the cornea equivalent is a full-thickness and the shape is also a desired shape of a cornea as recited in instant claim 11 (see col. 10, lines 1-25; col. 14, claims 1-16, in particular). Thus, the rejection of claims 11-12 and 17 for being anticipated by US Patent No. 5827641 is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5827641 (Parenteau et al. issued on Oct 27, 1998) in view of US Patent No. 6645715 (Griffith et al. issued on Nov 11, 2003, priority Jan 25, 1999) and US Patent No. 6689165 (issued Feb 10, 2004, priority Mar 31, 2000). The rejection is maintained for the reasons made of record.

Claims 11-17 as amended are drawn to an artificial full thickness or a half full thickness cornea transplant support and/or an artificial cornea transplant comprising a base biopolymer being incorporated with an attachment reagent comprising one or more the following: laminin, fibronectin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil or heparin sulfate, wherein the biopolymer is molded into the shape of a cornea and seeding or not seeding human corneal endothelial cells onto the biopolymer.

On p. 20-23 of the response, Applicant argues that the applied references do not make the claimed invention prima facie obvious and teach away from the invention because the combined references do not teach each element of the claimed invention and do not teach non-transformed human corneal endothelial cells in a biopolymer shaped as a cornea. Applicant argues that Griffth teaches an in vitro avascular, human corneal equivalent, comprising immortalized human cell line in a biopolymer support suitable for long term growth of HCEC not a support for a corneal biopolymer support for transplantation. Applicant argues that Jacob teaches an ocular device comprising an optical polymer (collagen, polyurethanes, plymethacrylates and other biocompatible polymers for a cornea) attached to a corneal enhancer molecule (growth factors, such as fibronectin, laminin, EGF and others), which is for growth of corneal epithelial cells not corneal endothelial cells in an artificial stroma and the claimed cornea transplant does not include use of tether molecules and the growth factors are not covalently bonded to the stroma. Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In contrast, the examiner asserts that applied references do not teach away from the claimed invention and do render the claimed invention obvious. As previously made

of record and as set forth above, Parenteau teaches an artificial cornea transplant support and an cornea equivalent comprising endothelial cells seeded on membranes made of biopolymer including collagen IV and coated with heparin (i.e.heparin sulfate) and heparin-binding growth factor (i.e. bFGF or EGF-conjugated with polycarbophil). Parenteau teaches the cornea equivalent (i.e. an artificial cornea transplant) comprising an inner endothelial cell layer, a middle stromal cell-collagen mixture layer and an external epithelial cell layer (see col. 14, claims 1-16; in particular) for cornea transplantation and also teaches the endothelial cells can be derived from different sources including different cornea endothelial cells and non-corneal endothelial cells derived from human (see col. 5, lines 1-5; col. 5, line 61-col. 6, line41; col. 8, lines 44-67, in particular).

Although Parenteau does not explicitly teaches use of human corneal endothelial cells in the corneal transplant as in claims 13 and 14, Griffith teaches corneal endothelial cells in the corneal transplant can be derived from human (see col. 15-16). Although Parenteau does not teach a half full-thickness as recited in instant claims 14-16 and also fails to teach laminin, RGDS, FGF or EGF-conjugated with polycarbophil as recited in instant claims 11 and 14, Griffith teaches artificial cornea transplant supports or artificial cornea transplants with different thickness comprising a base biopolymer with laminin, fibronectin, RGDS, bFGF conjugated with polycarbophil, EGF conjugated with polycarbophil or heparin sulfate seeding human corneal endothelial cells onto the biopolymer as recited in instant claims 11-17 (see col. 19-24). Griffith teaches an artificial mammalian cornea comprising an endothelium, a stromal matrix, an epithelium

and at least one layer of Bowman's or Descemet's membrane (see col. 19-24; col. 12, lines 18-55; col. 19-22; col 26, claims 1-22). In addition, Jacob teaches that different adhesion attachments such as laminin, fibronectin, integrin, RGDS, FGF, EGF, and TGF-b, can be used in a synthetic device for cornea augmentation or replacement to increases corneal epithelium cell adhesion (see abstract; col. 12-19; col. 19-20, claims 1-18, in particular).

It would have been obvious to a skilled artisan to use human corneal endothelial cells and different attachment agents in the artificial cornea transplant/transplant support disclosed by Parenteau to make a different thickness or a half full-thickness artificial cornea transplant because human corneal endothelial cells and different attachment agents have been successfully to be used for making a full or half-thickness artificial cornea transplant as taught by Griffith and Jacob. Note that

"The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.,* 325 U.S. 327, 65 USPQ 297 (1945)". See MPEP § 2144.07.

In addition,

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); see also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) and *Ex parteQuadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). See MPEP § 2144.06.

Conclusion

8. NO CLAIM IS ALLOWED.

9. This application contains claims 1-10 and 18-25 drawn to an invention nonelected with traverse in the reply filed on 12/18/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-

4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
December 28, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647